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UNITED STATES PATENT & TRADEMARK OFFICE

Examiner: Not yet known Art Unit: 1617

Re: Application of: Richard SACKLER, Robert KAIKO
and Paul GOLDENHEIM

Serial No.: 09/624,530

Filed: July 24, 2000

For: METHOD OF TREATING HUMANS WITH OPIOID
FORMULATIONS HAVING EXTENDED
CONTROLLED RELEASE

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INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

February 16, 2001

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97(b), Applicants hereby make of record the following copies of Information Disclosure Statements, PTO-1449 forms, and references cited therein, which were submitted during prosecution of the parent or grandparent application of the above-identified application. The parent application, U.S. Serial No. 08/838,368, filed April 8, 1997, issued as U.S. Patent No. 6,143,322; and the grandparent is U.S. Serial No. 08/677,797, filed on July 10, 1996, now abandoned.

I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service as "first class mail" with sufficient postage in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on February 16, 2001.
DAVIDSON, DAVIDSON & KAPPEL, LLC

BY: Benjamin Dimare

Attached as Exhibit A are the following documents which were submitted in the parent application:

- Information Disclosure Statement of March 26, 1999 (15 pages with a copy of U.S. Patent No. 5,672,360);
- Information Disclosure Statement of March 26, 1999 (7 pages)
- Information Disclosure Statement of March 26, 1999 (2 pages);
- Information Disclosure Statement of March 26, 1999 (7 pages);
- Information Disclosure Statement of March 26, 1999 (4 pages); and
- PTO-1449 forms (13 sheets)

It is noted that the above-identified Information Disclosure Statements of March 26, 1999 refer to the litigation involving the Assignee's U.S. Patent No. 5,672,360. Pursuant to 37 CFR 1.98(d) copies of the references of record in the parent or grandparent application are not enclosed. If for any reason the cited references, transcripts, or briefs, have become disassociated with the parent or grandparent applications, the Examiner is requested to contact the undersigned in order to arrange for the submission of replacement copies.

It is respectfully requested that these Information Disclosure Statements and references cited therein, and the PTO-1449 forms and references cited therein be considered and made of record.

Also enclosed for the Examiner's convenience are Exhibits B, C, D, E, F and G which were not submitted in the parent nor grandparent application.

Attached as Exhibit B to this Information Disclosure Statement is the District Court decision for the above-mentioned litigation.

Attached as Exhibit C to this Information Disclosure Statement are full copies of the appeal briefs for both parties in the above-mentioned litigation submitted to the Court of Appeals for the Federal Circuit.

Attached as Exhibit D to this Information Disclosure Statement are full copies of the reply briefs for both parties in the above litigation submitted to the Court of Appeals for the Federal Circuit in the above-mentioned litigation.

Attached as Exhibit E to this Information Disclosure Statement is a copy of the complete transcript of the oral arguments before the Court of Appeals for the Federal Circuit in the above-mentioned litigation.

Attached as Exhibit F to this Information Disclosure Statement is a copy of the Court of Appeals for the Federal Circuit Opinion of Purdue Plaintiffs-Appellants versus the Faulding Defendants-Appellees.

Attached as Exhibit G to this Information Disclosure Statement is a copy of the Purdue Plaintiffs-Appellants' Petition for Rehearing *En Banc*.

These documents (Exhibits B-G), which are not prior art in of themselves, provide further information concerning the positions taken by the Faulding Defendants-Appellees and the Purdue Plaintiffs-Appellants' responses thereto. It is respectfully requested that these attachments be considered and made of record.

Also enclosed is a new PTO-1449 form listing references (AA, AB, AC, AD, AE, AF, AG, AH, AI, AJ, AK, AL and AM), which were cited by the Examiner during the prosecution of the parent application. Copies of these references are enclosed herewith. It is respectfully requested that the PTO-1449 form and references cited therein be considered and made of record.

The Examiner's attention is also directed to the following copending patent applications:

Serial No. 09/390,719 filed September 7, 1999, entitled "Orally Administrable Opioid Formulations Having Extended Duration of Effect," which is a continuation of U.S. Application Serial No. 08/508,246, filed July 27, 1995, now U.S. Patent No. 5,968,551.

Serial No. 09/304,694 filed May 4, 1999, entitled "Methods of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of Plasma Drug Level" **and** Serial No. 08/938,898 filed September 26, 1997, entitled "Method of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of Plasma Drug Level". Serial No. 09/304,694 filed May 4, 1999, entitled "Methods of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of Plasma Drug Level" is a continuation of Serial No. 08/938,898 filed September 26, 1997, entitled "Method of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of Plasma Drug Level", which is a continuation of Serial No. 08/578,668 filed July 22, 1996, issued as the 5,672,360 patent, which is a continuation-in-part of Serial No. 08/156,468 filed November 23, 1993, issued as U.S. Patent No 5,478,577.

Serial No. 09/632,718 filed August 4, 2000, entitled "Opioid Formulations Having Extended Controlled Release", which is a continuation of U.S. Application Serial No. 09/225,959 filed January 6, 1999, which is a continuation of Serial No. 08/561,829 filed November 27, 1995, issued as U.S. Patent No. 5,958,459, which is a continuation of U.S. Patent Application Serial No. 08/086,248, filed July 1, 1993, now abandoned.

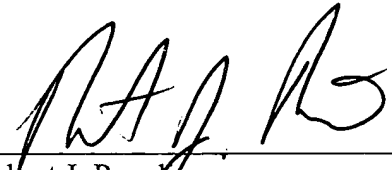
It is again respectfully requested that the accompanying attachments and references cited therein, and PTO-1449 forms and references cited therein be considered and made of record.

No fee is believed to be due for the submission of this Information Disclosure Statement as it is filed under 37 C.F.R. §1.97(b), before the mailing of a first Office Action on the merits or within three (3) months of the actual filing date. The Commissioner is authorized to charge any additional fee or credit any overpayment to our Deposit Account 50-0552.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____


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